



SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 138th PLENARY MEETING

**Held on 3-4 June 2020, web-conference
(Agreed on 18 June 2020)**

Participants

■ Panel Members:

Ana Allende, Avelino Alvarez-Ordóñez (4 June 2020), Declan Bolton, Sara Bover-Cid, Marianne Chemaly, Robert Davies, Alessandra De Cesare, Lieve Herman, Friederike Hilbert, Konstantinos Koutsoumanis, Roland Lindqvist, Maarten Nauta, Giuseppe Ru, Luisa Peixe, Marion Simmons, Panagiotis Skandamis, Elisabetta Suffredini

■ Hearing Experts¹:

Not applicable

■ European Commission (EC) and/or Member States representatives:

Matjaz Klemencic (EC, DG Health and Food Safety, Unit G2; for items 6.2/7.1)

Fabien Schneegans (EC, DG Health and Food Safety, Unit G4; for item 6.3 and part of item 10)

Halvard Kvamsdal, Athanasios Raikos (EC, DG Health and Food Safety, Unit E1; for item 6.5)

Wolfgang Trunk (EC, DG Health and Food Safety, Unit E5, for item 6.7)

Jean-Baptiste Perrin (EC, DG Health and Food Safety, Unit G4; for item 6.9 and part of item 10)

Marina Marini (EC, DG Health and Food Safety, Unit D1)

■ EFSA:

■ AMU Unit:

Elisa Aiassa, Laura Martino

■ BIOCONTAM Unit:

Sean Ashe, Frank Boelaert Katrin Bote, Maria Teresa da Silva Felício, Beatriz Guerra, Michaela Hempen, Ernesto Liébana, Winy Messens, Angel Ortiz-Peláez, Valentina Rizzi, Pietro Stella

■ Observers:

Not applicable

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



1. Welcome and apologies for absence

No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 136th and 137th Plenary meetings held on 29-30 April and on 4 May 2020, web-conference

The minutes of the 136th and 137th Plenary meeting were agreed by written procedure on 15 May 2020.

5. Scientific outputs submitted for possible adoption or endorsement

5.1. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 12: Suitability of taxonomic units notified to EFSA until March 2020⁴

The qualified presumption of safety (QPS) was developed to provide a generic safety evaluation for biological agents to support EFSA's Scientific Panels. It is based on an assessment of the taxonomic identity, the body of knowledge, safety concerns and antimicrobial resistance. Safety concerns identified for a taxonomic unit (TU) are where possible to be confirmed at strain or product level, reflected by 'qualifications'. No new information was found that would change the previously recommended QPS TUs of the 39 microorganisms notified to EFSA between October 2019 and March 2020, 33 were excluded, including 5 filamentous fungi, 5 *Escherichia coli*, 2 *Enterococcus faecium*, 2 *Streptomyces* spp. and 19 TUs already evaluated. Six TUs were evaluated. *Akkermansia muciniphila* was not recommended for QPS status due to safety concerns. *Clostridium butyricum* was not recommended because some strains contain pathogenicity factors. This TU was excluded for further QPS evaluation. *Galdieria sulphuraria* and *Pseudomonas chlororaphis* were also rejected due to a lack of body of knowledge. The QPS status of *Corynebacterium ammoniagenes* (with the qualification 'for production purposes only') and of *Komagataella pastoris* (with the

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00077>



qualification 'for enzyme production') was confirmed. The Panel Statement Part 12 was adopted by the BIOHAZ Panel.

6. Scientific outputs submitted for discussion

6.1. Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁵

The Extensive Literature Search (ELS) for the QPS opinion 2020-2022 was completed for the first reporting period in the Panel Statement part 12. In relation to the taxonomic revision of the *Lactobacillus* genus, previously designated *Lactobacillus* species will be reassigned to the new species and both the old and new names will be retained in the QPS list. The new taxonomy for Lactobacilli will be reflected in the next ELS for the Panel Statement Part 13. The deadline for the next QPS opinion is December 2022.

6.2. Application for the evaluation of the alternative method ECN tunnel composting⁶

The last WG meeting for this mandate was held on 27 May 2020. The additional information requested to the applicant was provided, therefore the clock restarted, and the new deadline for adoption of the related scientific opinion is now 10 July 2020. The WG Chair presented the draft opinion to the Panel for thorough reading, the opinion will be tabled for possible adoption at the next Plenary meeting.

6.3. Scientific opinion on potential BSE risk posed by the use of ruminant collagen and gelatine in feed for non-ruminants farmed animals⁷

The WG Chair presented the draft opinion for first reading. Firstly, the chair thanked the subgroup of Panel members that reviewed the probabilistic model, the basis to answer the ToRs before the Plenary and the comments received by other members as well. Some recommendations and corrections had been already actioned in the version presented during the Plenary. The new version of the model was well received by the Panel focusing on the uncertainties of the processes modelled and minimizing the variability of the parameters estimates. The layout and contents of the draft opinion were also well received by the Panel. Preliminary answers to the questions and to the ToRs were presented even though they have not been finalized. The Panel recommended to make additional enhancements to the model, calculating a weighted output to account for the frequency of cross-contamination at abattoir. They also requested to precise when worst case scenarios have been applied in the model, and consider the uncertainties not accounted for in the model and how they can affect the overall conclusions of the opinion. The working group added new assessment questions conducive to produce the answers to the ToRs. The fifth meeting has been fixed for Wednesday 10 June pm and Thursday 11 June am and the feedback of the Panel will be discussed.

6.4. Scientific opinion on the evaluation of public and animal health risks in case of a delayed *post-mortem* inspection in ungulates⁸

The last WG meeting was held on 6 May 2020, focussing on *Salmonella* detection after delayed *post-mortem* inspection. The WG chair presented the outcome of that meeting and gave an update of the draft opinion. A detailed suggestion for the *Salmonella* model was presented that

⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00083>

⁶<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00583>

⁷<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00436>

⁸<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00124>



includes variability and uncertainty. The model will quantitatively estimate the decrease of sensitivity in the detection of Salmonella 24 and 72h after slaughter compared to testing immediately after slaughter. The factors that influence this detection are initial distribution, survival during chilled storage, transfer of cells from carcass to enrichment media and competition with background flora. The input variables are informed by scientific literature. The Panel agreed with the modelling approach. The next sub-WG meeting is planned for 11 June 2020. The endorsement of their respective sections by AHAW, CONTAM and BIOHAZ Panel is foreseen for September/October 2020. The deadline for adoption of the opinion is December 2020.

6.5. Scientific opinions providing guidance on date marking and related food information⁹

The WG Chair updated the Panel on the ongoing progress, as there has not been any WG meeting since the last Plenary meeting. The WG Chair presented the ToRs as well as the approaches proposed by the WG to answer these and to do the uncertainty analysis. The Panel and the EC agreed with these approaches. The most important comments received from the Panel in written on the Part 1 DM draft opinion were discussed to allow subsequent presentation at the next WG meeting which will take place on 8-9 June as a web conference. The decision tree of the Part 1 opinion proposed to assist the choice between 'use by' and 'best before' dates as well as the decision tree of the Part 2 opinion on the durability/shelf life of opened packages have been carefully presented and discussed. The Panel agreed with both decision trees and gave important suggestions to improve the explanation in the body text of their implementation. The Panel suggested to develop further the text and summary tables that have been added to both draft opinions describing a few examples of the implementation of these decision trees for specific foods and include these in an appendix to facilitate its understanding. The deadline for adoption of the first opinion (ToRs 1 and 2) is October 2020 and of the second opinion (ToRs 3 and 4) is March 2021.

6.6. Scientific opinion on specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed¹⁰

No new WG meeting took place since the last Plenary of the BIOHAZ Panel. The Chair updated the Panel on the outcome of the EFSA-EMA bilateral meeting on this Scientific Opinion. The Opinion will be presented to the EMA CVMP in their meeting in June (16-18) and will be thoroughly discussed in their meeting in July (14-16). Comments will be provided in written form to the WG after this meeting. The public consultation on the methodology, including one example of its application, will be launched by EFSA in the last quarter of the year, after endorsement by the BIOHAZ Panel. The next meeting of the sub-WG-AMR will be web-conference on 26 June. The deadline for adoption of the opinion(s) is 30 September 2021.

6.7. Scientific opinion on the role played by the environment in the emergence and spread of antimicrobial resistance through the food chain¹¹

No new WG meeting took place since the last Plenary of the BIOHAZ Panel. The WG Chair presented the draft Scientific Opinion. For the purpose of this mandate, food-producing environments are defined as all environments where food of animal or non-animal origin is produced or processed, at both primary level (e.g. animal farms, fruits and vegetables cultivation fields etc.) and post-harvest level (e.g. slaughterhouses, processing plants etc.). The presentation and discussion with the BIOHAZ Panel focused on the sections "interpretation

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00438> and <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00439>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00221>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00343>



of ToRs”, “introduction”, and the assessment done so far for the “environmental sources and transfer pathways contaminating food products during production and processing” and “resistance bacteria and genetic determinants identified in these food-producing environments” for the three food production sectors identified: terrestrial animals, plants (vegetables, fruits, etc.) and aquaculture. The deadline for the adoption of the opinion is December 2020.

6.8. Scientific opinion on the use of the so-called “superchilling” technique for the transport of fresh fishery products¹²

The WG chair updated the Panel about the outcome of the last WG meeting on 28 May 2020 by web-conference. A hearing expert (Prof Arason) was invited to provide information about the superchilling of fresh fishery products. The terms of reference were further clarified. The Panel was reminded that the following groups are of interest for ToR1: the alternative group being the superchilled fresh fishery products (SFFP) placed in polystyrene boxes without ice, and the reference group being conventional fresh fishery products (CFFP) placed in polystyrene boxes with ice made of fresh water. It was explained that a heat balance would be used to establish initial conditions of SCFF that would be equivalent in terms of final point (where the ice is melted) of CCFF. Depending on the outcome of the heat balance, there is the potential need for a more complex heat transfer model similar (but not equal) to the approach used for tubs. The data from the Nile perch study was presented and the Panel was informed that a literature screening is in progress. For ToR 2, the Panel proposed and agreed to restrict the assessment to analytical methods (markers), including the Hydroxyacyl-coenzyme A dehydrogenase (HADH) enzymatic test, allowing an effective detection of the fraudulent use of previously frozen fish to commercialize it in the superchilling status. The markers would be categorized into enzymatic (incl. HADH), physical and spectroscopy based and summarized in a table with the description and the advantages and disadvantages. The next WG meeting will take place on 26 June 2020. The deadline for adoption is December 2020.

6.9. Scientific opinion on the efficacy and safety of high pressure processing of food

The EFSA secretariat gave an update on the administrative steps taken. The BIOHAZ will be the leading Panel to adopt the opinion with specific sections (on the evaluation of the potential chemical food safety risks in HPP-treated food) to be endorsed by the CEP and CONTAM Panels before adoption by the BIOHAZ Panel. The Panel Chair nominated Laurence Castle as vice-Chair of the *ad hoc* WG which will be established for this mandate (conditional to screening and approval of his declaration of interests). The deadline for adoption is 31 January 2022.

7. New Mandates

7.1. Request for a scientific opinion on the capacity of certain specific processing transformation methods of animal by-products used in the production of organic fertilisers and soil improvers in view of determining the endpoints in the manufacturing chain of certain derived products

The Secretariat presented the new mandate, that emanates from the recent new Regulation (EU) 2019/1009 on the rules on the making available on the market of EU fertilising products. The new legislation requires all organic fertilisers and soil improvers derived from products within the meaning of Regulation (EC) No 1069/2009, i.e, from animal by-products, to be declared end points in the manufacturing chain by 16 July 2022. EFSA has been asked to assess

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00437>



the biological risks to animal and public health deriving from the use as OF/SI of the following Category 2 and 3 materials and derived products processed in accordance with Regulation (EU) No 1069/2009 and Regulation (EU) No 142/2011: (1) biogas digestion residues and compost; (2) ash derived from incineration, co-incineration and combustion; (3) glycerine and other products of materials derived from the production of biodiesel and renewable fuels; (4) pet food; (5) feed and dog chews, (6) hides and skins, (7) wool and hair, (8) feather and downs, (9) and pig bristles. The scope of the risk assessment is the EU since this mandate is driven by the EC and the legal framework of the new Regulation 1009/2019. Deadline for submission of opinion: 31 October 2021. The Panel chair informed the Panel of the recent nomination, by written procedure, of Avelino Alvarez-Ordóñez as Chair of the ad hoc WG which will be established for this mandate (conditional to screening and approval of his declaration of interests).

8. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

8.1. Scientific Committee

No new meetings of the Scientific Committee took place after the last BIOHAZ Plenary meeting, therefore there were no new updates from the BIOHAZ Panel chair on this agenda item.

8.2. European Commission

European Commission representative informed the BIOHAZ Panel about the recent publication at EU level of the Communication on “A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system”. EFSA Secretariat informed the Panel about future possible mandates in preparation by the European Commission (EC) in the BIOHAZ area.

9. Other scientific topics for information and/or discussion

9.1. Implementation of the guidance on uncertainty analysis in scientific assessments

The BIOHAZ Panel Chair reported to the Panel the discussions held during the 7th meeting of the EFSA cross cutting Working Group on Uncertainty¹³, which agreed on the conclusions reached by the BIOHAZ Panel during the previous BIOHAZ Plenary meeting. One additional meeting of the cross cutting WG on Uncertainty will be organised to further discuss criteria for simplified EKE/expert consensus. The BIOHAZ Panel will discuss further the implementation of the uncertainty guidance in the next plenaries.

9.2. Presentation on Draft framework for protocol development for EFSA’s scientific assessments

EFSA Secretariat from Assessment and Methodology Support (AMU) Unit presented to the Panel the recently published “Draft framework for protocol development for EFSA’s scientific assessments”¹⁴ (link to the document). The Panel agreed on the pilot implementation of the

¹³ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-uncertainty.pdf>

¹⁴ <http://www.efsa.europa.eu/de/supporting/pub/en-1843>



Draft framework for protocol development from June 2019 until May 2020 in BIOHAZ mandates.

9.3. Update on the EMA expert group on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans

BIOHAZ Panel member Luisa Peixe, who is representing EFSA in the EMA expert group, briefly reported the progress made in the EMA expert group meetings and the plan for future meetings. A new EMA activity is starting in relation to implementing measures regarding the establishment of a list of antimicrobials which shall not be used or which may be used subject to certain conditions.

9.4. Topics of scientific concern in the area of biological hazards and BIOHAZ self-tasks

To ensure close collaboration between the BIOHAZ and the Emerging Risks area, EFSA representatives of the SCER Unit will attend the next BIOHAZ Plenary and present relevant issues arising from discussions in EFSA Emerging Risks Exchange Network (EREN) and Stakeholder Consultative Group on Emerging Risks (StaDG-ER), and to exchange views with the BIOHAZ Panel on emerging concerns in the biological hazards field.

10. Any other business

EFSA BIOHAZ Secretariat presented to the BIOHAZ Panel the outcome of the 2020 EFSA-Experts Mutual Assessment.

EFSA BIOHAZ Secretariat presented to the BIOHAZ Panel the findings reported in the EU Summary Report on surveillance for the presence of TSE in 2018¹⁵, and the findings of the EU One Health 2018 Zoonoses Report¹⁶.

Preliminary dates for 2021 BIOHAZ Plenary meetings were presented to the Panel, for agreement by the next Plenary.

The Panel agreed with the proposal from Marianne Chemaly, Chair of the former WG on *Campylobacter* control options, to draft a scientific paper(s) based on the recently adopted BIOHAZ Opinion on *Campylobacter*.

¹⁵ <https://www.efsa.europa.eu/it/efsajournal/pub/5925>

¹⁶ <http://www.efsa.europa.eu/it/efsajournal/pub/5926>